



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

Re: Normiflo<sup>®</sup>

Docket No. 97E-0367

APR 23 1999

The Honorable Q. Todd Dickinson  
Deputy Assistant Commissioner for  
Patent Policy and Projects  
Office of the Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Crystal Park Building 2, Suite 919  
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the patent term extension application for U.S. Patent No. 4,757,057 filed by Pharmacia & Upjohn Aktiebolag under 35 U.S.C. § 156. The patent claims the human drug product Normiflo<sup>®</sup> (ardeparin sodium), new drug application NDA 20-227.

In the October 13, 1998, issue of the Federal Register (63 Fed. Reg. 54717), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before April 12, 1999, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

cc: Burton A. Amernick  
Pollock, Vande Sande & Priddy  
1990 M St., NW, Suite 800  
P.O. Box 19088  
Washington, DC 20036

97E-0367

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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

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**Memorandum**

Date: APR 23 1999

From: Brian J. Malkin, Associate Director for Patents and Hearings  
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application  
for Normiflo<sup>®</sup>

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned drug under the Docket Number **97E-0367** stating that this particular patent is eligible for regulatory review. The Patent Number is **4,757,057**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.